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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,765	05/05/2005	Marc Poirot	0505-1037	6680

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YOUNG & THOMPSON
209 Madison Street
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Alexandria, VA 22314

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1628

NOTIFICATION DATE	DELIVERY MODE
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03/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/511,765	Applicant(s) POIROT ET AL.	
	Examiner Barbara P. Badio	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 12-19 and 26 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 12-19 and 26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits on a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2010 has been entered.

Status of the Application

2. Claims 1, 12-19 and 26 are pending in the present specification. The instant claims are rejected as indicated below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 12-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for solvents A, B, C and E and activator D as set forth in the present specification and instant claims 14-18, does not reasonably provide enablement for all solvents and activators. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Briefly, the instant claims are drawn to a method of preparing the instantly claimed compound. The instant process recites the utilization of a number of solvents, i.e., A, B, C and E and an activator D.

The present specification discloses examples of said solvents and activator. For example, methylene chloride is defined as both solvent A and solvent B (see claims 15 and 17). However, because of the lack of guidance in the present specification as to

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other solvents falling within the scope of solvent A, solvent B, solvent C and solvent E and activator D, the skilled artisan in the art at the time of the present invention would have to determine (a) solubility of meta-chloroperoxybenzoic acid in every solvent in order to determine solvent A; (b) solubility of compound formula (III) in every solvent wherein said solvent is also miscible with solvent A in order to determine solvent B; (c) solubility of the epoxy intermediate compound in every solvent in order to determine solvent C; (d) solubility of every amine in every solvent in order to determine solvent E and (e) compounds that would be encompassed by the term "activator D".

Because of the unpredictability of the solubility of compounds in various solvents and the effect of compounds to activate a reaction, it requires each embodiment to be individually assessed. *In re Fisher*, 427 F 2d. 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is needed in order to satisfy the statute.

6. Claims 12-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite in second the step the utilization of "an amine". The specification as originally filed set forth the use of an amine having a specific structure:

in a second step, the epoxy compound obtained in the first step, dissolved in a solvent C in the presence of an activator D, is reacted with an amine of formula Q_0Q_1 , Q_0 and Q_1 having the meanings given in claim 1, "

(see page

6, lines 21-25 of the present specification). The claims as amended are inclusive of amines not described in the specification as originally filed. Thus, the present specification does not reasonably convey to the skilled artisan in the art that the applicant had possession of the claimed invention at the time the application was filed.

7. The rejection of claims 1, 19 and 26 under 35 USC 112, second paragraph is withdrawn.

8. The rejection of claims 12-18 under 35 USC 112, second paragraph is maintained and claims 1, 19 and 26 are rejected under 35 USC 112, second paragraph.

Applicant argues (a) in light of their recited ability to dissolve defined compounds and/or immiscibility/miscibility relative to other solvents, solvents A, B, C and E are believed to be clear and (b) the activator/catalyst is clear, in that, it is one used for the reaction between the obtained epoxy compound and the amine as defined. Applicant's argument was considered but not persuasive for the following reason.

The properties desired for each of solvent A, B, C and E and the activator D are clear based on the recited ability. However, solvents and/or activators that fall within the scope of each are unclear. 35 USC 112, second states the specification shall

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conclude with one or more claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention". The claim language does not particularly point out and distinctly claim what is encompassed by the terms "solvent A", "solvent B", "solvent C", "solvent E" and "activator D". Therefore, the skilled artisan would be unable to determine the metes and bound of the instant claims.

The instant claims are also indefinite for the following reasons:

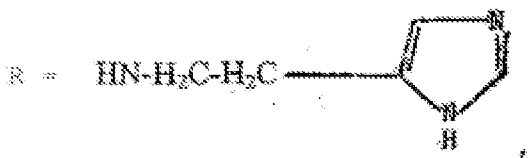
(a) The use of the term "characterized" in claims 1, 13-19 and 26 is synonymous with "comprising" and is "open-ended" and does not exclude additional, unrecited elements. The use of said term instead of "consisting of" in a Markush claim creates confusion as the scope of the claimed invention. Applicant's attention is directed to MPEP § 2173.05(h);

(b) Claim 1 recites "the carbon in position 4.....which are, independently, H or CH₃ **with CH₃ in the α and/or β position**". The phrase "**with CH₃ in the α and/or β position**" creates confusion as to the intended position of "H" at said position 4;

(c) Claim 1 recites "said compound selected from the group consisting of: a compound.....

a compound corresponding to formula (I) in which the **two bonds C₅-C₆ and C₇-C₈ are single bonds**, Z represents OH in position 5 and T₁ = T₂ = T₃ = H, R being in position 6, and R -NH-(CH₂)₃-NH-(CH₂)₄-NH-(CH₂)₃-NH₂,

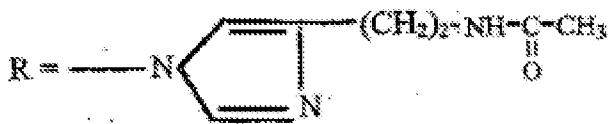
a compound corresponding to formula (I) in which the **two bonds C₅-C₆ and C₇-C₈ are single bonds**, Z represents OH in position 5 and T₁ = T₂ = T₃ = H, R being in position 6, and



a compound corresponding to formula (I) in which the **two bonds C₅-C₆ and C₇-C₈ are single bonds**, Z represents OH in position 5 and $T_1 = T_2 = T_3 = \text{H}$, R being in position 6 and having the meaning



a compound corresponding to formula (I) in which the **two bonds C₅-C₆ and C₇-C₈ are single bonds**, Z represents OH in position 5 and $T_1 = T_2 = T_3 = \text{H}$, R being in position 6 and having the meaning



and

a compound corresponding to formula (I) in which the **two bonds C₅-C₆ and C₇-C₈ are single bonds**, Z represents OH in position 5 and $T_1 = T_2 = T_3 = \text{H}$, R being in position 6 and being: $\text{NH-(CH}_2)_3\text{-NH-(CH}_2)_4\text{-NH}_2$.

However, claim 1 also recites “**one of the bond between carbons 5 and 6 and the bond between carbons 7 and 8 is a double bond, whereas the other is a single**

bond". Therefore, the phrase "**two bonds C₅-C₆ and C₇-C₈ are single bonds**" in the definition of the compound creates confusion as the metes and bound of the instant claims;

(d) There is duplicate recitation of the phrase "

a compound corresponding to formula (I) in which the
bond between carbons C₇ and C₈ is a double bond, R = NH-(CH₂)₃-NH-
(CH₂)₄-NH₂, and T₁ = T₂ = T₃ = H,

" in claim 1. It is suggested one of said phrases be deleted; and

(e) Claim 12 recites "at least one of the bond between carbons 5 and 6 and the bond between carbons 7 and **8is** a double bond". Did applicant intend "at least one of the bond between carbons 5 and 6 and the bond between carbons 7 and **8 is** a double bond"? If so, correction is requested. If not, clarification of what is intended is required.

For these reasons and these given in the previous Office Actions, the rejection of claims 12-18 under 35 USC 112, second paragraph is maintained and claims 1, 19 and 26 are rejected under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 102

9. The rejection of claims 1 and 19 under 35 USC 102(b) over El Kihel et al. (Anticancer Research, 1999) is withdrawn.

Claim Rejections - 35 USC § 103

10. The rejection of claims 1, 19 and 26 under 35 USC 103(a) over El Kihel et al. (Anticancer Research, 1999) is withdrawn.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628